NORTH DAKOTA
DEPARTMENT OF HEALTH
Division of Air Quality

RADIOACTIVE MATERIAL
LICENSING GUIDE

Remote Afterloader Programs

(Revised: February 2, 2006)

I. INTRODUCTION

This guide describes the types of information that should be submitted in an application for a license for the possession and use of remote afterloader brachytherapy sources. The Department's regulations listed below are of major significance to a remote afterloader brachytherapy licensee; however, the regulations in their entirety as well as this guide are applicable to a remote afterloader brachytherapy licensee and both items should be consulted in completing an application. The applicant should carefully read the regulations (revised 3/1/03). This guide does not substitute for an understanding of the regulations.

A. 33-10-01 General Provisions
B. 33-10-03 Licensing of Radioactive Material
C. 33-10-04.1 Standards For Protection Against Radiation
D. 33-10-07.1 Medical Use of Radioactive Material
E. 33-10-11 Fees For Issuance of License and Registration Certificates and Inspections
F. 33-10-13 Transportation of Radioactive Material

II. FILING AND APPLICATION:

The information submitted on the application must be sufficient to allow the Department to determine the proposed equipment, facilities, procedures, and the training and experience of personnel are such that the therapy program will not constitute an unreasonable risk to the health and safety of employees and the public. Information submitted should pertain to the specific activities for which authorization is sought and should be complete. Submission of incomplete information will result in delays because of the correspondence necessary to obtain supplemental information. Applications and the corresponding application fees should be mailed to:

North Dakota State Department of Health
Division of Air Quality - Radiation Control Program
918 East Divide Ave., 2nd Floor
Bismarck, ND 58501-1947
Phone: 701-328-5188
Fax: 701-328-5185

Since licensees are required to comply with Department rules and regulations, license conditions, and the content of the submitted application, at least one copy of all information submitted to the Department should be kept by the applicant for reference.

III. RADIOACTIVE MATERIAL LICENSE APPLICATION FORM SFN 8414 (RCP-10):

The application should be completed following the instructions provided with the form. The signed original copy should be filed with the Department and one copy kept by the applicant. Since the space provided on the form is limited, additional sheets should be appended as necessary. Supplemental information should be labeled to identify the applicant and should reference the item for which information is being given. The following comments deal with the indicated items:

Item 1(a)

The applicant named in Item 1(a) is the business name of the organization or person (hospital, corporation, partnership, individual, etc.) who will be responsible, as the licensee, for assuring that the remote afterloader brachytherapy equipment is used in compliance with the conditions of the license and with the State Rules.

The applicant should be specified by name and mailing address in Item 1(a). Individuals should be designated as the applicant only if they are acting in a private capacity and the use of the therapy facility is not connected with their employment with a corporation or other legal entity.

Item 1(b)

Only if the address of radioactive material use is different than the address in Item 1(a).

Item 2

Self-explanatory; attach organizational chart.

Item 3

Self-explanatory; mark as, “New Application” if this is an application for a new license.

Item 4

Authorized users are individuals who use or directly supervise the use of licensed radioactive material. Training and experience requirements for authorized users are described in Appendix D, “Training for Use of Remote Afterloader Units.” Provide each authorized user’s qualifications in Items 8 and 9. Training and experience requirements for an authorized medical physicist are described in Appendix B, “Training for an Authorized Medical Physicist.”

Alternate criteria for experienced authorized users and medical physicists are described in Appendix C, “Training for Experienced Radiation Safety Officer, Medical Physicist and Authorized User and Recentness of Training”

Item 5

Along with the name of the individual designated as the Radiation Safety Officer, a statement should be included with the application outlining the Radiation Safety Officer’s duties, responsibilities and authority over processes related to radiation safety. The Radiation Safety Officer is expected to ensure compliance with the North Dakota Radiological Health Rules.

Training and experience requirements for the Radiation Safety Officer are described in Appendix A, “Training for Radiation Safety Officer.” Alternate criteria for experienced radiation safety officers are described in Appendix C, “Training for Experienced Radiation Safety Officer, Medical Physicist and Authorized User and Recentness of Training”

Item 6(a)

Self-explanatory (i.e., "Iridium-192")

Item 6(b)

For sealed sources, the applicant shall provide the name of the manufacturer and the model number of the sealed source(s). State the number of sources requested and the maximum activity (in gigabecquerels or millicuries) per source.

Item 7

Specify the manufacturer and model number of the remote afterloader brachytherapy unit which will house the source specified in Item 6(b).

Items 8 and 9

The training and/or experience of each authorized user or medical physicist listed in Item 4; and the Radiation Safety Officer listed in Item 5 should be summarized in Items 8 and 9. Space on the application form is limited, therefore more detailed information with regard to training and experience of each authorized user may be provided using the forms labeled as “Supplement A” and/or “Supplement B”.

Training requirements for these individuals are described in Appendices A-D.

Items 10 and 11

State the manufacturer and model number of each radiation detection instrument and probe to be used and describe the minimum specifications and operating characteristics of each. The description should include the type of radiation detected, range (mR/hr), window thickness (mg/cm^2) and type of use for which each instrument is designed. The frequency, method, and standards used in calibrating such instrumentation must be described. Instruments should be calibrated at least annually or after servicing (except battery changes). If such calibrations are to be performed by an outside firm, please provide their name and address.

Provide the manufacturer and model number of the area radiation monitor installed within the remote afterloader brachytherapy room. This monitor should be tested for proper operation and functionality each day of use and calibrated at least annually.

Item 12

The name and address of the NVLAP approved supplier furnishing personnel dosimetry badges or equivalent personnel monitoring devices (please specify) and the frequency for exchanging such monitoring devices should be stated.

If pocket chambers, pocket dosimeters or alarming ratemeters are to be used as additional monitoring devices, state the manufacturer and model number, the useful range, frequency for reading the devices and the procedures for their calibration and maintenance.

Item 13

An explanation and appropriate sketches must be submitted for the remote afterloader brachytherapy unit and for the remote afterloader brachytherapy facility. Specific topics to be addressed are:

A. Remote afterloader brachytherapy unit:

Provide detailed information with regard to the afterloader unit and related equipment. Include description of how and where the device will be used and stored; and verification of security of the radioactive material during use and storage.

Provide operating and emergency procedures relating to use and storage of the afterloader unit and procedures for maintenance, repair, source exchange, etc.

B. Remote afterloader brachytherapy facility:

Facilities and equipment must be adequate to protect health and minimize danger to life or property. The applicant should describe equipment and facilities available for safe use and storage of radioactive material listed in Item 6 of this application. Attach a sketch of your facility showing where the sources will be used and stored; and submit a shielding evaluation demonstrating that public dose limits will not be exceeded in surrounding areas (above, below, etc.).

The applicant must describe facilities and equipment for the therapy program to safely use and store radioactive material. The applicant should focus on facilities to be used for therapy administration and patient accommodations. The licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation detection instruments, that radiation levels have returned to ambient levels.

One method of meeting this requirement is to use an area radiation monitor installed within the remote afterloader brachytherapy room. This monitor should be equipped with an emergency

power supply separate from the power supply for the afterloader unit. Such area radiation monitors can provide an audible or visible indication (e.g., alarm sound or flashing light) of an exposed or partially exposed source.

Regulations require that, except for low dose rate (LDR) units, each licensee shall construct or equip each treatment room so as to permit continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used should be specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions should be specified; or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again. The communication system should allow the patient to communicate with the unit operator in the event of medical difficulties. An open microphone system can be used to allow communication without requiring a patient to move to activate controls.

The regulations also require adequate equipment and controls to maintain exposures of radiation to workers within regulatory limits and to keep all exposures as low as reasonable achievable (ALARA). The North Dakota Radiological Health Rules require that each door leading into the treatment room be provided with an electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Further, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the source(s) on/off control is reset at the console.

Due to the unique characteristics of pulsed dose rate (PDR) remote afterloaders and the lack of constant surveillance of their operation, a more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, consider the following:

- The PDR device control console is not accessible to unauthorized personnel during treatment;

- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected;

- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:

    - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position;

    - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or appropriate internal error condition(s) exist;

    - The "source safe and radiation present" signal should also be self-testing. If a "source not safe" input is received without a corresponding "radiation present" signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. Reset this circuit manually before attempting to continue treatment;

- The audible alarm should be sufficiently loud to be clearly heard by the facility's responsible device/patient monitoring staff at all times; and

- No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute should be prohibited.

If the alarm circuit is inoperative for any reason, licensees should prohibit further treatment of patients with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

Applicants may submit information on alternatives to fixed shielding as part of their facility description. This information must demonstrate that the shielding will remain in place during the course of patient treatment.

For patient rooms where LDR remote afterloader use is planned, neither a viewing nor an intercom system is required. However, the applicant should describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

Provide a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
- Area radiation monitoring equipment;
- Viewing and intercom systems (except for LDR units);
- Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room; and
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons.
- Emergency response equipment

Item 14

Radiation Protection Program: Each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program must be sufficient to ensure compliance with the North Dakota Radiological Health Rules. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. Licensees must abide by all applicable regulations, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed radiation protection program during the licensing process.

Basic remote afterloader requirements require the licensee to:

1. Submit an annotated drawing of the room or rooms and adjacent areas where afterloader will be used. Include shielding available and additional safety equipment.

2. Commit to the following:

    a. Access to the room housing the afterloading brachytherapy unit shall be controlled by a door at each entrance.

b. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door.

   The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.

c. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once a month. Records of test results shall be maintained for inspection by the Department.

d. In the event of malfunction of the door interlock, the radiation device shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

3. Prior to initiation of a treatment program, and subsequent to each source exchange for the afterloading brachytherapy units, radiation surveys and tests shall be performed in accordance with the following:

   a. A radiation survey shall be made of:

      i. The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 10 cm from the surface of the source head shall not exceed 3 mR/hr.

      ii. All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:

         (1) That radiation levels in restricted areas are not likely to cause exposure in excess of the established dose limits for radiation workers
         (2) That radiation levels in unrestricted areas do not exceed the established limits for members of the public

   b. Records of the survey results shall be maintained for inspection by the Department.

4. That the following shall be performed only by persons specifically authorized by the Department, an Agreement State of the U. S. Nuclear Regulatory Commission to perform such services:

   a. Installation and replacement of sources contained in the afterloading brachytherapy unit.

   b. Any maintenance or repair operations on the afterloading brachytherapy unit, including work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

5. Following removal of the source, the licensee shall make a radiation survey of the patient with an appropriate radiation detection survey instrument to confirm that all sources have been removed. For surveys associated with remote afterloader procedures, the licensee must use a portable radiation measurement survey instrument, capable of measuring dose rates of 1 mR/hr to at least 1000 mR/hr. It is important to use calibrated survey instruments with appropriate sensitivity, since the high exposure rates associated with these sources can easily overload some survey instrument detectors, resulting in a false low reading. This survey of the patient must be done whether or not there is any indication of radiation levels provided by an area radiation monitor. The surveys shall be performed immediately after completion of the therapy procedure before removal of the patient from the treatment room.

   The required area monitor provides an immediate indication of a possible problem and thus serves a useful function as an early warning device. This area monitor will provide a visible indication of an

exposed or partially exposed source, and must be observable immediately on entry into the treatment vault. It must be equipped with an independent source of backup power and checked with a dedicated check source for proper operation each day of use of the afterloader device.

6. The licensee shall have written emergency procedures describing actions to be taken, including surgical intervention, should the source not return to the shielded container at the conclusion of treatment. The licensee shall not begin any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded condition. The licensee shall ensure that appropriate staff and equipment are available immediately, at the location that the afterloader procedure is performed, to implement the written emergency procedures. Equipment shall include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient, to include scissors and cable cutters. The emergency source removal procedure should minimize exposure to health care personnel while maximizing safety of the patient.

7. During all patient treatments using high dose-rate remote afterloader units; an authorized user and an authorized medical physicist must be physically present during the initiation of all patient treatments involving the unit; and an authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, must be physically present during continuation of all patient treatments involving the unit.

8. The licensee shall ensure that personnel are trained in both the routine use of the afterloading device and emergency procedures necessary to return the source to a safe condition. Training shall be provided immediately to new personnel and periodic retraining, not to exceed 12 month intervals, shall be provided for all personnel. The licensee shall retain records of this training for a period of 3 years.

Written policies and procedures for the following areas should be established and submitted with the application:

- Emergency procedure for accidents and disconnects
- “Medical Event” policy with regard to 33-10-07.1-119, “Report and Notification of a Medical Event”
- Written procedures posted at the console to include manually retracting the source, removing the source from the patient and removing the patient from the room in the event the source cannot be retracted back to the shielded position, securing the room against unauthorized entry and who to notify in case of an emergency
- Physical inventory of sealed sources performed every six months
- Indicate how you will receive prior written approval from an authorized user before the use of radioactive material
- Describe security of the radioactive material and training of ancillary personnel with regard to the hazards of radiation
- Please describe what surveys will be performed of the patient after removal of the source
- Describe what type of observation is used during treatment of the patient
- Please describe the following areas concerning the afterloader unit:
    - Warning on/off light at console
    - Locking device to lock source in place
    - Timer that terminates exposure and retracts source

- If afterloader is used in an accelerator room, describe the switch mechanism that disengages the accelerator when the afterloader is being used

- Please submit your procedures for administrations requiring a written directive. Review Sections 33-10-07.1-17 and 18 with regards to written directives.

- Refer to Appendices E-L, submit policies and procedures to ensure that the applicable portions of these regulations are met

- Address security of sources

- Provide qualifications and training of staff and periodic retraining/in-services provided

- Address training of ancillary personnel

Item 15

Waste disposal generally does not apply to remote afterloader licensees. However, the applicant shall indicate that sources will be returned to the manufacturer (or another duly licensed facility) for disposal/recycling of the radioactive material as needed.

Item 16

The application certificate must be signed by the applicant, or if the applicant is an institution, by an individual to whom this responsibility is delegated. For example, when a hospital is the applicant, the hospital administrator is the individual who should sign the application.

IV. AMENDMENT AND RENEWAL OF LICENSES

Applications for amendment of existing licenses should be filed in the same manner as initial applications or may be filed in letter form. The application should clearly identify the license which is to be amended by license number. The exact nature of the requested changes should be specified and additional supporting information, as necessary, should be provided.

Licenses are normally issued for a period of five years. If an application for license renewal is filed thirty days or more before license expiration, the existing license remains in effect until the new application has been finally acted upon by the Department.

Renewal applications should be filed using Form SFN 8418 and should contain complete and up-to-date information concerning the applicant's current program. References to previously submitted documents should be clear and specific and specify the document by date and indicate pertinent information by page and paragraph. There is no fee associated with the license renewal process.

The annual fee for remote afterloader licenses in Category 7.C.1 is $2500 (as described in North Dakota Radiological Health Rules Chapter 33-10-11). This fee must be paid by January 1 each year the license is active.

Additional fees may be assessed for multiple office locations or late fees as described in Chapter 33-10-11. Fee payments shall be made by check, draft, or money order made payable to the North Dakota Department of Health. Fees are nonrefundable.

SUPPLEMENT A

TRAINING AND EXPERIENCE
AUTHORIZED USER
or
RADIATION SAFETY OFFICER

SUPPLEMENT B

PRECEPTOR STATEMENT

APPENDIX A

33-10-07.1-20. Training for Radiation Safety Officer

Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in section 33-10-07.1-14 (authority and responsibilities for the radiation protection program) to be an individual who:

1. Is certified by a specialty board whose certification process includes all of the requirements in subsection 2 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. a. Has completed a structured educational program consisting of both:

(1) Two hundred hours of didactic training in the following areas:

(a) Radiation physics and instrumentation;
(b) Radiation protection;
(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Radiation biology; and
(e) Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a United States nuclear regulatory commission or agreement state or licensing state license or permit issued by a United States nuclear regulatory commission master material licensee that authorizes similar type of use of radioactive material involving the following:

(a) Shipping, receiving, and performing related radiation surveys;
(b) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
(c) Securing and controlling radioactive material;
(d) Using administrative controls to avoid mistakes in the administration of radioactive material;
(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
(f) Using emergency procedures to control radioactive material; and
(g) Disposing of radioactive material; and

b. Has obtained written certification, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the structured educational program requirements in subdivision a of subsection 2 and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; or

3. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material

Approved Specialty Boards include: the American board of health physics in comprehensive health physics; American board of radiology; American board of nuclear medicine; American board of science in nuclear Medicine; Board of pharmaceutical specialties in nuclear pharmacy; American board of medical physics in radiation oncology physics; Royal college of physicians and surgeons of Canada in nuclear medicine; American osteopathic board of radiology; or American osteopathic board of nuclear medicine.

APPENDIX B

33-10-07.1-21. Training for an Authorized Medical Physicist

Except as provided in section 33-10-07.1-23 (training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist), the licensee shall require the authorized medical physicist to be an individual who:

1. Is certified by a specialty board whose certification process includes all of the training and experience requirements in subsection 2 and whose certification has been recognized by the United States nuclear regulatory commission or an agreement state or a licensing state; or

2. a. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in sections 33-10-07.1-29 (requirements for possession of sealed sources and brachytherapy sources), 33-10-07.1-53 (decay of strontium-90 sources for ophthalmic treatments), 33-10-07.1-65 (full calibration measurements on teletherapy units), 33-10-07.1-66 (full calibration measurements on remote afterloader units), 33-10-07.1-67 (full calibration measurements on gamma stereotactic radiosurgery units), 33-10-07.1-68 (periodic spot checks for teletherapy units), 33-10-07.1-69 (periodic spot checks for remote afterloader units), 33-10-07.1-70 (periodic spot checks for gamma Stereotactic radiosurgery units), and 33-10-07.1-72 (radiation surveys), as applicable; and

   b. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivision a of subsection 2 and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in section 33-10-07.1-21 (training for an authorized medical physicist) or equivalent United States nuclear regulatory commission or agreement state or licensing state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

APPENDIX C

33-10-07.1-23. Training For Experienced Radiation Safety Officer, Medical Physicist and Authorized User

and

33-10-07.1-24. Recentness of Training

1. An individual identified as a radiation safety officer, a teletherapy or medical physicist, or a nuclear pharmacist on a United States nuclear regulatory commission or agreement state or licensing state license or a permit issued by a United States nuclear regulatory commission or agreement state or licensing state broad scope licensee or master material license permit or by a master material license permittee of broad scope before September 1, 2003, need not comply with the training requirements of section 33-10-07.1-20 (training for radiation safety officer), 33-10-07.1-21 (training for an authorized medical physicist), or 33-10-07.1-22 (training for an authorized nuclear pharmacist), respectively.

2. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the United States nuclear regulatory commission or an agreement state or a licensing state, a permit issued by a United States nuclear regulatory commission master material licensee, a permit issued by a United States nuclear regulatory commission or agreement state or licensing state broad scope licensee, or a permit issued by a United States nuclear regulatory commission master material license broad scope permittee before September 1, 2003, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements in sections 33-10-07.1-35 through 33-10-07.1-75.

Recentness of Training

The training and experience specified in this chapter must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

APPENDIX D

33-10-07.1-75. Training for Use of Remote Afterloader Units

Except as provided in Appendix C (Section 33-10-07.1-23, “Training for experienced radiation safety officer, medical physicist and authorized user), the licensee shall require an authorized user of a sealed source for a use authorized under section 33-10-07.1-59 (use of a sealed source in a remote afterloader unit) to be a physician who:

1. Is certified by a medical specialty board whose certification process includes all of the requirements in subsection 2 and whose certification has been recognized by the United States nuclear regulatory commission, an agreement state or a licensing state; or

2. a. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

    (1) Two hundred hours of classroom and laboratory training in the following areas:

        (a) Radiation physics and instrumentation;
        (b) Radiation protection;
        (c) Mathematics pertaining to the use and measurement of radioactivity; and
        (d) Radiation biology; and

    (2) Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in this section or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state at a medical institution, involving:

        (a) Reviewing full calibration measurements and periodic spot checks;
        (b) Preparing treatment plans and calculating treatment doses and times;
        (c) Using administrative controls to prevent a medical event involving the use of radioactive material;
        (d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
        (e) Checking and using survey meters; and
        (f) Selecting the proper dose and how it is to be administered;

    b. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this section or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state, as part of a formal training program approved by the residency review committee for radiation oncology of the accreditation council for graduate medical education or the committee on postdoctoral training of the American osteopathic association. This experience may be obtained concurrently with the supervised work experience required by paragraph 2 of subdivision a of subsection 2; and

    c. Has obtained written certification that the individual has satisfactorily completed the requirements in subdivisions a and b of subsection 2 and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in this section or equivalent requirements of the United States nuclear regulatory commission, an agreement state, or a licensing state for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

APPENDIX E

33-10-07.1-59. Use of a Sealed Source in a Remote Afterloader Unit

A licensee shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

1. As approved in the sealed source and device registry; or

2. In research in accordance with an active investigational device exemption application accepted by the United States food and drug administration provided the requirements of subsection 1 of section 33-10-07.1-19 (suppliers for sealed sources or devices for medical use) are met.

APPENDIX F

33-10-07.1-60. Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit

1. Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that each source has been removed from the patient or human research subject and returned to the safe shielded position.

2. A licensee shall retain a record of these surveys in accordance with section 33-10-07.1-105 (records of surveys after source implant and removal).

APPENDIX G

33-10-07.1-61. Installation, Maintenance, Adjustment and Repair

1. Only a person specifically licensed by the United States nuclear regulatory commission or an agreement state or a licensing state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source driving unit, or other electronic or mechanical component that could expose a source, reduce the shielding around a source, or compromise the radiation safety of the unit or a source.

2. Except for low dose-rate remote afterloader units, only a person specifically licensed by the United States nuclear regulatory commission or an agreement state or a licensing state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

3. For a low dose-rate remote afterloader unit, only a person specifically licensed by the United States nuclear regulatory commission or an agreement state or a licensing state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source contained in the unit.

4. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with section 33-10-07.1-109 (records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units).

APPENDIX H

33-10-07.1-62. Safety Procedures and Instructions for Remote Afterloader Units

1. A licensee shall:

    a. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

    b. Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with a source;

    c. Prevent dual operation of more than one radiation-producing device in a treatment room if applicable; and

    d. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place a source in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

        (1) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

        (2) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

        (3) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

2. A copy of the procedures required by subdivision d of subsection 1 must be physically located at the unit console.

3. A licensee shall post instructions at the unit console to inform the operator of:

    a. The location of the procedures required by subdivision d of subsection 1; and

    b. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

4. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

    a. The procedures identified in subdivision d of subsection 1; and

    b. The operating procedures for the unit.

5. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

6. A licensee shall retain a record of individuals receiving instruction required by subsection 4, in accordance with section 33-10-07.1-104 (records of safety instruction).

7. A licensee shall retain a copy of the procedures required by subdivision d of subsection 1 and subdivision b of subsection 4 in accordance with section 33-10-07.1-110 (records of safety procedures).

APPENDIX I

33-10-07.1-63. Safety Precautions for Remote Afterloader Units

1. A licensee shall control access to the treatment room by a door at each entrance.

2. A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

a. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
b. Cause each source to be shielded when an entrance door is opened; and
c. Prevent any source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

3. A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

4. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

5. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

6. In addition to the requirements specified in subsections 1 through 5, a licensee shall:

a. For medium dose-rate and pulsed dose-rate remote afterloader units, require:

(1) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
(2) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove each source applicator in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

b. For high dose-rate remote afterloader units, require:

(1) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
(2) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

c. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

d. Notify the radiation safety officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

7. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

a. Remaining in the unshielded position; or

b. Lodged within the patient following completion of the treatment.

APPENDIX J

33-10-07.1-66. Full Calibration Measurements on Remote Afterloader Units

1. A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

a. Before the first medical use of the unit;

b. Before medical use under the following conditions:

(1) Following replacement of the source or following reinstallation of the unit in a new location outside the facility;
(2) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;
(3) At intervals not exceeding one-quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds seventy-five days; and
(4) At intervals not exceeding one year for low dose-rate remote afterloader units.

2. To satisfy the requirement of subsection 1, full calibration measurements must include, as applicable, determination of:

a. The output within plus or minus five percent;

b. Source positioning accuracy to within plus or minus one millimeter;

c. Source retraction with backup battery upon power failure;

d. Length of the source transfer tubes;

e. Timer accuracy and linearity over the typical range of use;

f. Length of the applicators; and

g. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

3. A licensee shall use the dosimetry system described in subsection 1 of section 33-10-07.1-64 (dosimetry equipment) to measure the output.

4. A licensee shall make full calibration measurements required by subsection 1 in accordance with published protocols accepted by nationally recognized bodies.

5. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subsection 2, a licensee shall perform an autoradiograph of each source to verify inventory and source arrangement at intervals not exceeding one-quarter.

6. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subsections 1 through 5.

7. A licensee shall mathematically correct the outputs determined in subdivision a of subsection 2 for physical decay at intervals consistent with one percent physical decay.

8. Full calibration measurements required by subsection 1 and physical decay corrections required by subsection 7 must be performed by the authorized medical physicist.

9. A licensee shall retain a record of each calibration in accordance with section 33-10-07.1-112 (records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations).

APPENDIX K

33-10-07.1-69. Periodic Spot Checks for Remote Afterloader Units

1. A licensee authorized to use a remote afterloader unit for medical use shall perform spot checks of each remote afterloader facility and on each unit:

    a. Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

    b. Before each patient treatment with a low dose-rate remote afterloader unit; and

    c. After each source installation.

2. A licensee shall perform the measurements required by subsection 1 in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

3. A licensee shall have the authorized medical physicist review the results of each spot check within fifteen days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

4. To satisfy the requirements of subsection 1, spot checks must, at a minimum, assure proper operation of:

    a. Electrical interlocks at each remote afterloader unit room entrance;

    b. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

    c. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

    d. Emergency response equipment;

    e. Radiation monitors used to indicate the source position;

    f. Timer accuracy;

    g. Clock date and time in the unit’s computer; and

    h. Decayed source activity in the unit’s computer.

5. If the results of the spot checks required in subsection 4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or spot check the malfunctioning system.

6. A licensee shall retain a record of each spot check required by subsection 4 and a copy of the procedures required by subsection 2 in accordance with section 33-10-07.1-114 (records of periodic spot checks for remote afterloader units).

APPENDIX L

33-10-07.1-72. Radiation Surveys

1. In addition to the survey requirement in subsection 1 of section 33-10-04.1-09 (survey and monitoring), a person licensed under sections 33-10-07.1-59 through 33-10-07.1-75 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the sealed source and device registry.

2. The licensee shall make the survey required by subsection 1 at installation of a new source and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose a source, reduce the shielding around a source, or compromise the radiation safety of the unit or a source.

3. A licensee shall retain a record of the radiation surveys required by subsection 1 in accordance with section 33-10-07.1-117 (records of surveys of therapeutic treatment units).